EPA Comments
Approach for the Preliminary Risk Evaluation for Ecological Receptors
August 24, 2004

General Comments:

Scope and Objectives: The Approach for the Preliminary Risk Evaluation for Ecological Receptors (PRE Approach TM) describes the methods that will be used in the Preliminary Risk Evaluation (PRE). As originally envisioned, the PRE was to focus on the Round 1 fish tissue data to assess risks to fish through the tissue residue approach and piscivorous wildlife through a dietary approach. Table 9-2 of the Portland Harbor RI/FS Work Plan states that "the results of the PRE will be used to help identify COPCs related to contaminant concentrations in fish and invertebrate tissue" and that "the purpose of the PRE is to help identify data and information gaps that may be filled during subsequent investigations/evaluations prior to the baseline ERA." EPA does not object to expanding the scope of the PRE to include a dietary approach for evaluating the risk to ecological receptors based on sediment and tissue data. However, it is not possible to screen out contaminants from further consideration through this approach because of the limited benthic tissue data, the ongoing sediment characterization effort, and the upcoming surface water and groundwater sampling efforts. Although the PRE is useful for evaluating the risk associated with the exposure of persistent, bioaccumlative and toxic chemicals (PBTs) to fish and wildlife that are exposed primarily through fish ingestion, COPCs cannot be completely eliminated until all pathways (exposure to water, exposure to sediment, and exposure through prey, and exposure through sediment ingestion) are assessed. EPA believes that the PRE will be more useful if it used to evaluate relationships between contaminants present in sediments and various ecological receptors to develop a better understanding of the chemicals that may be driving risk, the spatial scale of exposure, and the identification of tissue related data gaps at the Portland Harbor site.

Relationship to Ecological Risk Assessment: The PRE Approach TM should describe how the PRE fits into the overall ecological risk assessment process. The PRE Approach TM should build off the Assessment Endpoint Table included in the programmatic work plan and describe which assessment endpoints are being addressed in the PRE and how the assessment endpoints will be addressed in the Round 2 Site Characterization Summary Report. In addition, the PRE should be consistent with the problem formulation described in the comprehensive ecological risk assessment technical memorandum (currently under review by EPA) and the conceptual site model for the site. The PRE Approach TM should clearly describe how the results will be used as we move forward through the ecological risk assessment process. For example, how and when will data gaps identified through the PRE be addressed? What is the relationship between the PRE and the Round 2 Site Characterization Summary Report? What is the relationship of between the PRE and the baseline ecological risk assessment? How will subsequent data collection be incorporated into the PRE and subsequent risk evaluations?

Dietary Based Approach: Round 1 of the Portland Harbor RI/FS focused on the collection of fish tissue data and limited sediment data. Round 2 of the Portland Harbor RI/FS (currently underway) is focused on the collection of sediment chemistry data and bioassays to evaluate sediment toxicity to benthic organisms. Although the PRE serves a useful purpose for preliminarily evaluating the risks to fish through the toxicity residue approach, there is a significant degree of uncertainty associated with a risk evaluation that utilizes historic and/or Round 1 sediment chemistry and benthic invertebrate tissue data as part of a dietary approach. As a result, the PRE must:

- Acknowledge the uncertainty associated with evaluating the risks to ecological receptors that may have significant exposure to sediment through direct contact or incidental ingestion;
- Acknowledge that the clam and crayfish data do not represent an adequate data set for evaluating risks to the benthic community and that risks to the benthic community will be best addressed through evaluation of the benthic toxicity data; and
- Acknowledge the uncertainty associated with a dietary based evaluation of ecological receptors for which benthic organisms make up a significant portion of the diet.

Lack of Benthic Tissue: The available data on "benthic" species (clams and crayfish) are not representative of benthic tissue in general. Crayfish should not be used to represent the benthic community because crayfish are epibenthic organisms and have the ability to metabolize contaminants. Clams should not be used to represent the benthic community because it is not possible to draw meaningful conclusions regarding benthic tissue based analysis of three clam tissue samples. It is clear that the lack of benthic tissue is data gap for the site. In order ensure that the RI/FS continues to move forward, the LWG should begin preparation of a work plan to address this data gap. Options for filling this data gap include:

- Cut the contaminant list down substantially so a smaller volume of tissue is required for analysis, and try once more to get field-collected benthic tissue samples.
- Collect sediment in the field, expose benthic organisms to the sediment in the laboratory, and measure the resulting tissue concentrations.
- Use cage mussels to assess contaminant uptake and bioaccumulation.
- Model contaminant uptake to sediment-dwelling organisms using simple transfer coefficients.

EPA believes that a better estimate of benthic invertebrate tissue concentrations will provide valuable information for the food web model, and will allow for a more realistic estimate of exposure for organisms that feed on benthic organisms.

Data Evaluation: The PRE Approach TM states risk screening will be based on the "highest sediment and tissue concentrations from relevant data," and that "more realistic exposure point concentrations will also be calculated using a 95% upper confidence limit of the mean." It is not

clear whether use of a 95% UCL is appropriate when evaluating fish tissue data that are based on composites, sometimes across large reaches of the river. The PRE should evaluate each fish tissue composite sample individually to develop an initial understanding of spatial relationships within Portland Harbor.

Exposure Parameters: Similar to the approach agreed upon for TRVs (provisional TRVs), many of the exposure parameters specified in Section 5 of the PRE should be viewed as preliminary. This information may be presented conservatively or as a range in order to focus further investigative efforts. However, the PRE must also acknowledge the limitations of the data and recommend an approach to gathering the necessary data.

Specific Comments:

Section 2.0 – Objectives and Scope, Page 4: Identification of data gaps should be included as an objective of the PRE.

Section 2.1 - Assessment Endpoints, Page 4: Tissue data for the white sturgeon and Pacific lamprey were collected in a joint effort funded by EPA, the Oregon Department of Human Services and the City of Portland. This data can be used in conjunction with a dietary modeling approach to evaluate potential risks to these receptors.

Section 2.2.1 - Benthic Invertebrate Receptors, Page 5: The PRE Approach TM states that clam and crayfish will be used to represent the benthos. These taxa have substantial limits for that purpose because: 1) crayfish are epibenthic scavengers; and 2) the differences in physiology and interaction with the sediments among benthos are large. This is further substantiated by the poor sediment-tissue correlation for crayfish presented in the Food Web Model Technical Memorandum. With respect to clams, the clam tissue available is too limited to develop a meaningful relationship between benthic tissue and sediment. As a result, the PRE should acknowledge that sufficient data is not available to develop meaningful benthic BSAFs at the Portland Harbor site and that benthic tissue is a key data gap.

Section 2.2.2 – Fish Receptors, Page 6: The PRE Approach TM states “If no statistically predictive relationship is determined from the linear regression, application of a mass-balance mechanistic food web model will be investigated in an upcoming technical memorandum." This statement seems to indicate that a food web model will not be developed if a predictive relationship is determined from the sculpin data. This statement should be revised to make it clear that a food web model is a key component of the Portland Harbor RI/FS.

Section 3.1.2 - Tissue Data, Page 8: The PRE Approach TM states that all eleven aquatic receptors will be used to estimate dietary exposure for fish and wildlife receptors. Dietary exposures should not be simply an average of all whole-body tissue samples. They should either be representative of the receptors diet or use the more highly contaminated tissue in order to be

conservative. In addition, dietary tissue exposures should also be evaluated spatially for receptors that may feed locally and where sufficient data is available.

Section 3.3.1, Historical Sediment Data, Page 9: EPA and the LWG have agreed that data to be used for risk assessment must meet Category 2 quality assurance (QA) requirements. However, not all the historical data meets this quality standard. In addition, some of the data had incomplete analyte lists and elevated detection limits. As a result, caution should be used when using historic sediment data to estimate dietary exposures. Again, concerns about the historic sediment data set, and the ongoing round 2 sediment sampling program suggest that the focus of the PRE should be to develop and understanding regarding the relative levels of risk across the site rather than screening chemicals prior to initiating the baseline ecological risk assessment.

Section 3.3.2 - Tissue Data, Page 9: Quality assurance/quality control (QA/QC) data is available from the U.S. Department of Fish and Wildlife for some tissue samples collected within Portland Harbor. This data will be forwarded to the LWG. Historic data for which sufficient QA/QC data is available should be evaluated to determine its suitability for use in the PRE and/or in the BERA.

Section 3.4 - Data Reduction, Page 9: The data reduction rules utilized in the PRE should be consistent with the recently approved technical memorandum on guidelines for data reporting. In addition, the PRE Approach TM states that toxicity equivalent quotient (TEQ) concentration sums will be calculated for dioxins and dioxin-like PCB congeners separately; the risk from all dioxin-like contaminants as a whole (i.e., dioxin *and* dioxin-like PCBs) should also be evaluated.

Section 4.0 – Evaluation of Co-Located Sediment and Biota, Page 11: This section should describe the exploratory nature of this exercise and discuss how the data will be utilized to gain further understanding of the relative risks across the site and to identify data gaps. In addition, this section should make clear what organisms will be evaluated for the purpose of developing BSAFs and how the data will be evaluated spatially. It is recommended that this analysis be limited to organisms that are in close contact with the sediment such as sculpin or large scale sucker. As described earlier, EPA does not believe it is possible to develop meaningful BSAFs for crayfish and clams based on existing data.

Section 4.1 - Statistical Evaluation, Page 11:

Strictly speaking, a BSAF approach is not applicable to metals, since the approach is predicated on organic carbon and lipid normalization which is not generally applicable to metals. However, a BAF approach has been applied to metals, where a BAF is simply the un-normalized ratio of tissue concentration divided by sediment or food item concentration. Exploration of BAFs to better understand contaminant distribution and relationships may be of use at the Portland Harbor site.

Spearman's rank is a non-parametric measure of association of the strength of the monotonic relationship between sediment concentration and tissue concentration. Although it may show that tissue concentrations increase with sediment concentrations, this test will not give provide a predictive relationship between sediment concentrations and sculpin tissue. By using ranks, the data may be monotonic but not linear, and some information may be lost by replacing actual sample points with rank values. Therefore, the statistical evaluation should present information on the normality of the data, and test statistics using parametric statistics (i.e. Pearson's). If the data are not normally distributed, the data may be best suited to the non-parametric Spearman's Rank test to determine whether there is a positive correlation (i.e. monotonically increasing data). If Spearman Rank finds no such correlation, a BSAF relationship should not be inferred. *However*, if Spearman Rank says that there is a positive correlation, it *does not* necessarily entail that an adequate predictive relationship exists.

Since the biota-sediment accumulation factor is a constant, the relationship between organic carbon normalized sediment concentrations and lipid-normalized tissue concentrations ought to be linear. If the data exhibits a strongly nonlinear (e.g., exponential or polynomial) distribution, it is likely that processes beyond simple equilibrium partitioning taking place. If this is the case, the use of BSAFs may not be appropriate.

Alpha levels and type I and II error rates for various statistical tests should be established prior to conducting the PRE. In order to rely on BSAFs only when they will provide a good understanding of the relationship between sediment and tissue concentrations, relatively low alpha levels (i.e., 0.05) are recommended,

The specific statistical test(s) should be listed. Once the data are entered into the database, running a series of tests using both normalized and non-normalized data should be simple to do, and less likely to miss relationships. In addition to organic-matter normalization for organic compounds, the concentrations of mercury in the sediments should be normalized to organic matter as well, and all of the concentrations in the sediments should also be tested using the data normalized to sediment grain-size.

The memo does not indicate that the concentrations of the substances in either the sediments or tissue will be tested for covariance. The tests should be performed, but the method should be described in the memo. Further clarification regarding methods to "investigate" the "nature of the correlation" should be provided.

Section 4.2 - Derivation of Predictive Algorithms, Page 12:

This section should be expanded to provide more specifics on the proposed approach for calculating individual BSAFs and extrapolating or spatially averaging BSAFs across the site. It should be further noted that factors controlling BSAFs may vary throughout the river, and may be very important in understanding bioaccumulation potential in different areas. Although

combining BSAFs in this manner may allow for additional statistical evaluations of the data which results in a "harbor wide model" for the relationship between sediment chemistry and tissue concentrations, the appropriateness of this evaluation for explaining tissue relationships is questionable, and potentially beyond the capabilities of the simplicity of the BSAF linear relationship.

The relationship between chemical concentration and lipid content (or organic carbon content) should be explored to determine if a relationship actually exists before it is automatically used to calculate BSAFs. Non-normalized relationships should be explored. The importance of lipid for explaining chemical concentrations may vary among different species and contaminant levels.

Section 4.3 - Application of BSAF, Page 12:

This section should describe the intended application of the BSAFs in the PRE. A detailed understanding of the relationship between sediment and tissue will be developed through the food web modeling approach. For the PRE, BSAFs could be used to support the dietary exposure approach by developing estimates of biota contamination in locations where we have sediment contaminant data but no tissue data. However, without true benthic tissue data, this effort is fraught with uncertainty. As stated previously, EPA strongly feels that this is a significant data gap for the site. However, for the purposes of the PRE it may be possible to utilize literature BSAFs to develop a better understanding of the dietary exposure pathway, understand the spatial elements of uptake from sediment to benthic tissue and facilitate the identification of data needs.

BSAFs are inherently a reflection of partitioning relationships at equilibrium for individual contaminants. Thus multiple regressions are not allowed. In practical terms, one likely cause of poorly performing BSAFs would be additive or synergistic effects of multiple contaminants, in which case a more elaborate model taking into account covariance might work better.

Section 5.0 - Characterization of Exposure, Page 14:

The purpose of developing exposure point concentrations based on a 95% UCL on the mean is unclear. Although this information may provide an understanding of the range of potential risks through a preliminary evaluation, it may not be used for screening purposes. If one purpose of the PRE is to focus the investigation, data should be evaluated spatially based on the fish tissue compositing process.

Historic sediment data has been collected for a variety of purposes. In addition, some historic sediment studies have been eliminated from consideration for quality assurance/quality control reasons. In addition, the fish tissue data is comprised of composite samples collected over varying reaches of the Willamette River. As a result, it is not possible to assume that the contaminant data is lognormally distributed. The data should be tested for normalcy and log

transformed only if appropriate.

Section 5.1.1 - Exposure Assessment for Benthic Invertebrates, Page 15:

With respect to crayfish, the tissue residues may be used to evaluate risk to the crayfish themselves based on the maximum concentrations detected at various locations within the site. These samples are already composites, and represent "average concentrations" in crayfish locations. Each location should be looked at separately, and compared to an appropriate TRV. By taking the mean of the composite samples (a mean), information is lost on specific areas of the river that may or may not exceed TRVs, and information on localized population effects on these organisms. However, as, described earlier, crayfish must not be used as a surrogate for benthic tissue.

Given the limited tissue data, it will not be possible to perform any screening for clams based on the tissue residue approach. Concentration information should be presented for informative purposes only with the acknowledgement that the data set is limited. Clam tissue data should be compared individually to the appropriate TRV to provide information on specific areas of the site.

Section 5.1.2.1- Tissue Residue Exposure, Page 16:

The PRE Approach TM suggests that the data from carp would be used only for the evaluation of the dioxins and dioxin-like compounds, and not for any of the other COIs. This limitation is unnecessary. The PRE should assess risk to carp from all of the contaminants measured in carp, and assess dioxin risk in every species for which we have dioxin data.

It may not be appropriate to combine tissue residue concentrations from the different composites to determine a "river wide" tissue residue for each species. Areas of the river may exhibit differences related to TRV exceedances, and that information should not be diluted out by averaging composite samples. Variability and area of exceedance will be important components of the risk assessment, especially in determining population and localized effects.

Section 5.1.2.2 - Dietary Exposure, Page 17:

Equation 5.2 suggests that sediment is a component of diet. This is inappropriate. It is improper to say a fish consumes (for example) 70% invertebrate tissue and 30% sediment. The fish is getting nutrition from the tissue it consumes, not the sediment (although algal matter or invertebrates within sediment may be used for nutrition, the sediment itself is not). Contaminant exposure to fish (and other ecological receptors) should include the contribution of contamination received from diet (dietary exposure) as well as the contribution of contamination received through incidental ingestion of sediment.

As stated earlier, it may not be appropriate to calculate 95 % UCLs to estimate fish dietary exposures. In addition, when converting wet weight to dry weight, percent moisture should not be the average across all fish and invertebrate species, but should be a species-specific conversion.

Section 5.1.3 – Exposure Assessment for Wildlife, Page 18: The prey concentration term specified in Equation 5-3 should be expressed in terms of dry weight (See Equation 5-2).

Section 5.2 – Dietary Exposure Assumptions, Page 19: This section should make it clear that we do not have good estimates for the contaminant concentrations for some key prey species such as benthic infauna. As a result, there are significant limitations to evaluating risk to fish and wildlife thorough the dietary pathway. One objective of the PRE should be to develop an understanding of the relative importance of this data gap and recommend an approach to addressing this critical data gap.

Section 5.2.1 – Fish Exposure Assumptions, Page 19: This section should make it clear that the highest prey tissue concentration will be used even if that means that we assume fish are consuming 100% of different prey species. In addition, the data from the clams and crayfish are such poor representatives of the potential concentrations available to benthivores as to make their use for this exercise meaningless. In particular, COPCs should not be eliminated based on these data.

Section 5.2.2 - Wildlife Exposure Assumptions, Pages 21-27:

Risk to birds from DDE, PCBs, and dioxin-like compounds should be evaluated based on an egg approach (i.e., using egg TRVs). This section should be updated to reflect this approach for all bird species. For other compounds, juvenile birds should be considered as more sensitive that adults, so the appropriate TRVs and model should be selected to represent exposure to juvenile birds, or appropriate sensitivity factors should be added.

Crayfish and clam tissue are not appropriate surrogates for juvenile salmon, sculpin and peamouth diet. This data gap will need to be filled.

Food ingestion rates should be converted from dry weight to wet weight. Experimental data will provide the best estimates of exposure, and therefore should be used over allometric equations if is available.

Evaluation of stomach contents during Round 1 of the RI/FS suggest that smallmouth bass feed extensively on crayfish. As a result, a sediment ingestion rate of 2% seems low. Furthermore, Beyer et al., (1994) report sediment ingestion rates that range between 2 and 11%. An appropriately conservative sediment ingestion rate should be selected with an understanding that this assumption will be refined further in the BERA.

Juvenile Chinook salmon should not be included in the dietary dose estimates for the hooded merganser. It is unlikely that the hooded merganser would feed on juvenile Chinook salmon and given the low concentrations (because of lower residence times) the addition of this tissue concentration will only unrealistically lower the exposure point concentration to fish tissue.

Juvenile Chinook salmon and sculpin are not within the size range to be considered prey for bald eagles or ospreys (see also, Table 5-2). Although juvenile salmon and sculpin are consumed by larger fish that are prey for eagles and ospreys, these fish should not be considered part of the bald eagle or osprey diet.

The sediment ingestion rate for river otter specified in Table 5-2 is based on "professional judgment." This value should be further supported for use in the BERA and the uncertainty surrounding this value acknowledged in the PRE.

Diet composition for osprey, bald eagle, mink and river otter should be based on what the organisms are feeding on. For example, osprey in this area (Willamette River) have been found to feed primarily (90% of the biomass) on large-scale sucker and northern pikeminnow (Henney et al, 2003 – Biomagnification Factors (fish to osprey eggs from Willamette River, Oregon, U.S.A.) for PCDDs, PCDFs, PCBs and OC pesticides, *Environmental Monitoring and Assessment* 84: 275-315). Therefore, using a diet composition that includes all fish species (sculpin, peamouth, juvenile Chinook salmon, smallmouth bass, largescale sucker, brown bullhead, northern pikeminnow, black crappie, and carp) will result in unrepresentative exposure point concentrations, as the true prey concentrations may be diluted out among species. This is especially true with the inclusion of the salmon tissue concentrations. Not only may these concentrations be unrepresentative of migrating salmon (based on the fish and time of year they were collected), but their short residence time and subsequently lower concentrations will skew exposure estimates.

Empirical information should be used over allometric equations if the information is available. Ingestion rates for osprey and mink are presented in EPA's Exposure Factors Handbook.

Section 6.0 – Characterization of Effects, Page 28: The PRE Approach TM states that the TRVs will be used in the PRE and throughout the ERA. This text should be amended to reflect the decision to use "provisional" TRVs in the PRE. In some cases it may be appropriate to consider a range of TRVs to appropriately bracket potential risk rather than as a screening step. This will provide useful information regarding the potential risks to ecological receptors at the site without screening out chemicals prematurely. In addition, the last paragraph in this section states that the PRE will "consider" TRVs based on both NOECs/NOELs and LOECs/LOELs. The PRE Approach TM should provide greater specificity about how evaluation of potential risks using both sets of values will be presented. In addition, it is recommended that both a dietary and tissue residue approach be utilized for chemicals that bioaccumulate.

Section 7.2, Identification of COPCs, Page 30: As stated in the general comments, it is not appropriate to perform a strict screening step at this time due to the lack of critical data such as benthic invertebrate data and the ongoing site characterization efforts. However, the development of hazard quotients is a useful exercise for understanding the distribution of contaminants in sediment and fish tissue. The PRE Approach TM states that comparison to COIs will be identified as COPCs if the effects concentration is greater than the NOAEL for T&E species, or greater than the LOAEL for all other species. However, "greater than the NOAEL" is currently the highest NOAEL, which may not be a conservative screen at this point for T&E species (where the goal is to protect the individual). As stated earlier, it may be appropriate to present a range of hazard quotients based on a range of TRVs in the PRE to gain a better understanding of potential risks to ecological receptors at the site.